K100402

BARD
Bard Access Systems

Site~Rite Vision™ Ultrasound System

510(k) Summary of Safety and Effectiveness

Device trade name: Site~Rite Vision™ Ultrasound System

Device class and panel: Class II, Radiology Devices Panel

Classification Names:

Name	Product Code	CFR Number
Ultrasonic Pulsed Doppler Imaging System	IYN	892.1550
Ultrasonic Pulsed Echo Imaging System	IYO	892.1560
Diagnostic Ultrasonic Transducers	ITX	892.1570
Picture Archiving and Communications System	LLZ	892.2050

Applicant name: Kimberly Geisler, Henry Boland
Bard Access Systems, Inc. [wholly owned subsidiary of C.R. Bard, Inc.]
605 North 5600 West, Salt Lake City, UT 84116
(801) 522-5000, x5421 or x5428

Predicate devices: K071204 - Site~Rite® 6 Ultrasound System
K071134 - SonoSite, Inc. Maxx™ Series Ultrasound System
K053069, K043559 - SonoSite, Inc. High-Resolution Ultrasound System (C3 Series)
K043452, K033367, K030949 - SonoSite, Inc. High-Resolution Ultrasound System (C2 Series)

Performance Standards: Performance standards have not been established by the FDA under §514 of the Federal Food, Drug and Cosmetic Act.

Indications for Use: The Site~Rite Vision™ Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications include:

- Fetal
- Abdominal
- Intraoperative (semi-critical[1])
- Pediatric
- Peripheral Vessel
- Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)
- Musculo-skeletal (conventional and superficial)
- Cardiac (adult and pediatric)

Typical examinations performed using the Site~Rite Vision™ Ultrasound System include:

Imaging Applications	Exam Type (adult & pediatric)
Vascular	Assessment of carotid arteries, aorta, deep veins, superficial veins in the arms and legs, select small vessels supporting organs
Vascular Access	Guidance for PICC, CVC, dialysis catheter, port, PIV, and arterial line placement, and peripheral vein and artery access
Abdominal	Assessment of liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, appendix, and surrounding anatomical structures
Interventional and Intraoperative	Guidance for biopsy, drainage, peripheral nerve blocks, and intraoperative procedures (semi-critical[1])
Superficial	Assessment of breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal procedures, soft tissue structures, and surrounding anatomical structures

[1] Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 29 2010

Bard Access Systems, Inc.
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K100402
Trade/Device Name: Site-Rite Vision™ Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and LLZ
Dated: February 12, 2010
Received: February 16, 2010

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of March 5, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Site-Rite Vision™ Ultrasound System, as described in your premarket notification:

Transducer Model Number

128 Element Linear Probe with Buttons
128 Element Linear Probe without Buttons
128 Element Convex Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Robert Becker (for)

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): _____

Device Name: **Site~Rite Vision™ Ultrasound System**

Indications for Use:

The Site~Rite Vision™ Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications include:

- Fetal
- Abdominal
- Intraoperative (semi-critical[1])
- Pediatric
- Peripheral Vessel
- Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)
- Musculo-skeletal (conventional and superficial)
- Cardiac (adult and pediatric)

Typical examinations performed using the Site~Rite Vision™ Ultrasound System include:

Imaging Applications	Exam Type (adult & pediatric)
Vascular	Assessment of carotid arteries, aorta, deep veins, superficial veins in the arms and legs, select small vessels supporting organs
Vascular Access	Guidance for PICC, CVC, dialysis catheter, port, PIV, and arterial line placement, and peripheral vein and artery access
Abdominal	Assessment of liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, appendix, and surrounding anatomical structures
Interventional and Intraoperative	Guidance for biopsy, drainage, peripheral nerve blocks, and intraoperative procedures (semi-critical[1])
Superficial	Assessment of breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal procedures, soft tissue structures, and surrounding anatomical structures

[1] Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office ~~of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100402

Table 1.3-1 Diagnostic Ultrasound Indications for Use Form – *Site~Rite Vision™ Ultrasound System*

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N					B+CD	
	Abdominal	N					B+CD	
	Intra-operative (semi-critical†)	N					B+CD	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N					B+CD	
	Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)	N					B+CD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-Esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N					B+CD	
	Musculo-skeletal (Superficial)	N					B+CD	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N					B+CD	
	Cardiac Pediatric	N					B+CD	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N					B+CD	
	Other (Specify)							

N = new indication; **P** = previously cleared by FDA; **E** = added under this appendix

† Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

Robert A Scott

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100402

Table 1.3-2 Diagnostic Ultrasound Indications for Use Form – *Site~Rite Vision™ Ultrasound System 128 Element Linear Probe with buttons*

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N					B+CD	
	Abdominal	N					B+CD	
	Intra-operative (semi-critical[1])	N					B+CD	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N					B+CD	
	Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)	N					B+CD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-Esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N					B+CD	
	Musculo-skeletal (Superficial)	N					B+CD	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N					B+CD	
	Cardiac Pediatric	N					B+CD	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N					B+CD	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1] Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100402

Table 1.3-3 Diagnostic Ultrasound Indications for Use Form – *Site~Rite Vision™ Ultrasound System 128 Element Linear Probe without buttons*

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N					B+CD	
	Abdominal	N					B+CD	
	Intra-operative (semi-critical†)	N					B+CD	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N					B+CD	
	Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)	N					B+CD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-Esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N					B+CD	
	Musculo-skeletal (Superficial)	N					B+CD	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N					B+CD	
	Cardiac Pediatric	N					B+CD	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N					B+CD	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

† Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

Robert A Booker Jr

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100407

Table 1.3-4 Diagnostic Ultrasound Indications for Use Form – *Site~Rite Vision™ Ultrasound System 128 Element Convex Probe*

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N					B+CD	
	Abdominal	N					B+CD	
	Intra-operative (semi-critical†)	N					B+CD	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N					B+CD	
	Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-Esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N					B+CD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N					B+CD	
	Cardiac Pediatric	N					B+CD	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N					B+CD	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

† Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100402